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Titel des Beitrags: Sorafenib in combination with intensive chemotherapy in elderly patients with acute myeloid leukemia: results from a randomized, placebo-controlled trial.

Abstract: The prognosis of elderly patients with acute myeloid leukemia (AML) is still dismal even with intensive chemotherapy. In this trial, we compared the antileukemic activity of standard induction and consolidation therapy with or without the addition of the kinase inhibitor sorafenib in elderly patients with AML. All patients received standard cytarabine and daunorubicin induction (7+3 regimen) and up to two cycles of intermediate-dose cytarabine consolidation. Two hundred one patients were equally randomly assigned to receive either sorafenib or placebo between the chemotherapy cycles and subsequently for up to 1 year after the beginning of therapy. The primary objective was to test for an improvement in event-free survival (EFS). Overall survival (OS), complete remission (CR) rate, tolerability, and several predefined subgroup analyses were among the secondary objectives. Age, sex, CR and early death (ED) probability, and prognostic...
factors were balanced between both study arms. Treatment in the sorafenib arm did not result in significant improvement in EFS or OS. This was also true for subgroup analyses, including the subgroup positive for FLT3 internal tandem duplications. Results of induction therapy were worse in the sorafenib arm, with higher treatment-related mortality and lower CR rates. More adverse effects occurred during induction therapy in the sorafenib arm, and patients in this arm received less consolidation chemotherapy as a result of higher induction toxicity. In conclusion, combination of standard induction and consolidation therapy with sorafenib in the schedule investigated in our trial is not beneficial for elderly patients with AML.